4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3758]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0814. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910-0814--Revision

This information collection supports Agency regulations in 21 CFR part 312, subpart I, Expanded Access to Investigational Drugs for Treatment Use; associated guidance; and Form FDA 3926, Individual Patient Expanded Access Investigational New Drug Application (IND). The regulations govern the use of investigational new drugs, biologics, and approved drugs if availability is limited by a risk evaluation and mitigation strategy, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The goal of the expanded access program is to facilitate the availability of such products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. The regulations provide that certain criteria be met, establish content and format requirements for associated reporting, and require that submissions include a cover sheet.

Although we continue to account for burden associated with the submission of expanded access requests for individual patients, we are revising the information collection to also account for burden attendant to other expanded access submissions, including commercial investigational new drug applications (INDs) that involve large groups of patients enrolled for treatment use of the investigational drug (§§ 312.300 through 312.320 (21 CFR 312.300 through 312.320)), currently approved under OMB control number 0910-0014. Because of FDA's long history of facilitating expanded access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions, our efforts in this regard are ongoing.

Form FDA 3926 was developed to assist respondents to the information collection. Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians who want to request expanded access as prescribed in the applicable regulations. To supplement the form instructions, we issued guidance, most recently updated in October 2017, entitled "Individual Patient Expanded Access

Applications: Form FDA 3926," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/individual-patient-expanded-access-applications-form-fda-3926. As discussed in the guidance, § 312.310(b) contains additional submission requirements for individual patient expanded access requests. These respondents may continue to use either Form FDA 3926 or Form FDA 1571, Investigational New Drug Application (IND), for all types of IND submissions to satisfy requirements in 21 CFR 312.23(a) (approved under OMB control number 0910-0014). FDA considers a completed Form FDA 3926 signed by the physician and checked in the box in Field 10.a (Request for Authorization to use Form FDA 3926) to be a waiver request in accordance with 21 CFR 312.10.

We are proposing the following revisions to data elements in Form FDA 3926 and will make corresponding revisions to the form instructions:

- Reorder Field 8, "Physician Name, Address, and Contact Information" to Field 1, and renumber remaining data fields accordingly;
- Add "Race and Ethnicity" as an optional item under the "Clinical Information/Brief Clinical History" field;
- Add "Request for Withdrawal" under the "Contents of Submission" field;
- Add technological enhancements to the electronic version of Form FDA 3926 that utilize user-based selections to prompt required data field entries. Currently, certain fields become grayed out if not required for the submission type selected.

Data elements in §§ 312.315 and 312.320 continue to be reported in Forms FDA 1571 and 1572, Statement of Investigator, (approved under OMB control number 0910-0014).

In the *Federal Register* of December 14, 2021 (86 FR 71069), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden--Center for Drug Evaluation and Research[1]

Part 312, subpart I; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 3926	1,204	2.4958	3,005	0.75 (45 minutes)	2,254
§ 312.310(d); submissions related to emergency use of an investigational new drug: Form FDA 3926	1,265	2.843	3,596	16	57,536
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population[2]	88	3.64	320	120	38,400
§ 312.320(b); submissions related to a treatment IND or treatment protocol[2]	20	7	140	300	42,000
Total			7,061		140,190

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910-0014.

Table 2.--Estimated Annual Reporting Burden--Center for Biologics Evaluation and Research[1]

Part 312, subpart I; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 312.310(b) and 312.305(b); number of submissions related to expanded access and treatment of an individual patient: Form FDA 3926	118	1.305	154	8	1,232
§ 312.310(d); number of submissions related to emergency use of an investigational new drug: Form FDA 3926	1,591	4.2137	6,704	16	107,264
§§ 312.315(c) and 312.305(b); number of submissions related to expanded access and treatment of an intermediate-size patient population[2]	28	1	28	120	3,360
§ 312.320(b); number of submissions related to a treatment IND or treatment protocol[2]	15	1	15	300	4,500
Total			6,901		116,356

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910-0014.

The information collection reflects an increase in 254,750 burden hours and 11,568 responses annually since the last OMB review and approval of the information collection. We attribute this to an increase in the number of submissions.

Dated: April 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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